

## **REMARKS**

Claims 1-23 and 41 are now pending in this application. By the present amendments, the previously presented claims have been amended to more particularly point out the preferred features of the claimed invention and new claim 41 has been added to further define additional preferred embodiments of the present invention. No new matter has been introduced by any of these amendments.

### **I. Rejections Under 35 U.S.C. § 112**

#### **A. Second Paragraph**

The Examiner has rejected claims 1-23 and 40 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. While not acceding to the Examiner's characterization of the original claim language, solely in an effort to expedite prosecution, Applicants have amended the claims as shown above. In view of these amendments, the outstanding rejection has been obviated and withdrawal thereof is respectfully requested.

More specifically, with respect to the "effective amount" in steps (b) and (g), the claims have been amended to recite a "test amount" as the presently claimed method is intended for determining whether a particular candidate agent will alter the level of surface expression in the amount being tested.

With respect to the "sufficient period of time" in steps (c) and (h), such has been changed to a "predetermined" period of time. As noted above, the presently claimed method is intended for determining whether a particular candidate agent will alter the level of surface expression of a particular membrane protein. Accordingly, one skilled in the art would necessarily incubate the cells in the presence of the agent for a certain period of time to allow the agent to exert its

affects, if any, on the level of surface expression. Such a period of time would be “predetermined” by that skilled worker prior to conducting the claimed method.

With respect to the phrase “following incubation with said candidate agent” in the claims, such has been removed by the amendments above.

With respect to the “control” in claims 1 and 2, these claims have been amended to recite the reagents contained in such a control.

With respect to “said first mutant form” in claims 3, 14 and 16, claim 1 has been amended as shown above to provide proper antecedent basis.

With respect to the rejection of claim 4, Applicants respectfully traverse. As grounds for this rejection, the Examiner has alleged that the claim is “incomplete for omitting essential structural cooperative relationships of elements” because “there is no indication of what reagent . . . provides for the ‘fluorescence, luminescence, radioactivity, absorbance’ to be measured.”

Applicants submit, however, that any reagent could provide the property (fluorescence, luminescence, radioactivity, absorbance) being measured. That is, it could be the membrane protein itself, the candidate agent or the antibody which exhibits a measurable fluorescence, luminescence, radioactivity or absorbance for use in the claimed method, depending upon the particular functional groups and/or atoms present therein. There is no justification for requiring Applicants to limit claim 4 to only one of these reagents providing such a property and so withdrawal of this rejection is respectfully requested.

With respect to claims 7 and 8, these claims have been amended to depend only from claim 1.

With respect to claims 12 and 13, Applicants respectfully traverse. As grounds for this rejection, the Examiner has alleged that the claim is “incomplete for omitting essential structural

cooperative relationships of elements” because “there is no indication of what the ‘enzyme’ of claim 12 does.”

Applicants submit, however, that there is no requirement in the claim that the enzyme “do” anything. Rather, claim 12 recites that the antibody that binds to the membrane protein is coupled to an enzyme. Claim 12 is therefore directed to a preferred embodiment of the claimed method in which an antibody-enzyme couple is used to determine the level of binding of the candidate agent, rather than just an antibody alone. Thus, the claim does recite the necessary function of the enzyme, *viz.*, to be coupled to the antibody. Nothing else is required by the specification or the claim language, or the statute. Withdrawal of this rejection is respectfully requested.

For at least the reasons above, withdrawal of the outstanding rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**B. First Paragraph**

The Examiner has rejected claims 1-23 and 40 under 35 U.S.C. § 112, first paragraph. While not acceding to the Examiner’s characterization of the language or scope of the specification and claims, solely in an effort to expedite prosecution, Applicants have amended the claims as shown above. In view of these amendments, the outstanding rejection has been obviated and withdrawal thereof is respectfully requested.

**II. Rejections Under 35 U.S.C. § 102**

The Examiner has rejected claims 1, 4 and 7 under 35 U.S.C. § 102(b) as anticipated by Johnson, US Patent No. 6,034,066 in view of Barclay, claims 1, 3-4, 7 and 12-13 under 35 U.S.C. § 102(b) as anticipated by Woska in view of Isacke, claims 1, 4 and 7 under 35 U.S.C. § 102(e) as anticipated by Vallone (2004/0018566) in view of Barclay and claims 1 and 4-7 under

35 U.S.C. § 02(e) as anticipated by Qin, US Patent No. 7,063,953. While not acceding to the Examiner's characterization of the pending claims or the cited documents, solely in an effort to expedite prosecution, Applicants have amended claim 1 to incorporate the limitations of claim 40. As none of the cited documents teach or suggest the method of amended claim 1, withdrawal of these rejections is respectfully requested.

### **III. Rejections Under 35 U.S.C. § 103**

The Examiner has rejected claims 1, 3-7 and 12-13 under 35 U.S.C. § 103(a) as allegedly obvious over Curtis (2003/0022205) in view of Woska, claims 1, 3-7, 12-13 and 18 under 35 U.S.C. § 103(a) as allegedly obvious over Vallone in view of Woska, and claims 1, 3 and 12-13 over Johnson, Vallone or Qin in view of Martin. While not acceding to the Examiner's characterization of the pending claims or the cited documents, solely in an effort to expedite prosecution, Applicants have amended claim 1 to incorporate the limitations of claim 40. As none of the cited documents teach or suggest the method of amended claim 1, withdrawal of these rejections is respectfully requested.

### **IV. Provisional Rejection for Double Patenting**

The Examiner has provisionally rejected claims 1-23 and 40 under the judicially-created doctrine of obviousness-type double patenting. Because this is a provisional rejection, Applicants elect to defer commenting thereon until the indication of allowable subject matter in at least one of the pending applications.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. Favorable consideration and prompt allowance are earnestly solicited.

If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, Donald R. McPhail, at the telephone number listed below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future including extension of time fees, to **Deposit Account 04-1679** and please credit any excess fees to such deposit account.

Respectfully submitted,  
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